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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/282,471	03/31/1999	INDU PARIKH	401865/SKYEPHARMA	8677

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EXAMINER	
KISHORE, GOLLAMUDI S	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 01/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/282,471	PARIKH, INDU	
	Examiner	Art Unit	
	Gollamudi S. Kishore, Ph.D	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34-36,38-48,50,52 and 55-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34-36,38-48,50,52 and 55-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8-4-05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment dated 10-19-05 is acknowledged.

Claims included in the prosecution are 34-36, 38-48, 50, 52, and 55-67.

The following is a new office action.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 34-36, 38-48, 50, 52 and 55-67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The independent claims 35, 36 and 38 are confusing. The preamble states, "A method of preparing fenofibrate microparticles, which includes reducing the initial average particle size by sonication, milling, homogenization, microfluidization, antisolvent and solvent precipitation, or a combination thereof"; however, the method steps 1 and 2 do not indicate in which step these processes are utilized. For example, microfluidization and solvent precipitation requires a liquid and it is unclear from the claims, in which step the liquid is utilized. The examiner suggests amending the claims, clearly reciting the steps involved in the method practicing each of the above processes.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 34-36, 38-48, 50, 52 and 55-67 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4-25, 45-47, 52-53, 55-56, 65, 101-104, 109-119 of copending Application No. 10/260,788. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims in both applications are drawn to the same method of preparing the microparticles. The method claims in the copending application are drawn to generic 'water insoluble or poorly water-soluble drugs' and instant 'fenofibrate' thus, is anticipated by the 'insoluble drug' in the claims of copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 34-36, 38-48, 50, 52 and 55-67 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 45-97 of copending Application No. 10/443,772. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims in both applications are drawn to the same method of preparing the microparticles of fenofibrate. The method claims in the copending application recite in addition the step of adding the bulking/releasing agents in order to prepare rapidly disintegrating solid dosage forms of fenofibrate. It would have been obvious to one of ordinary skill in the art to utilize additional steps in instant process to prepare appropriate dosage forms of fenofibrate such as rapidly disintegrating forms claimed in the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 34-36, 38-48, 50, 52 and 55-67 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 50-52, 54-92 and 97-131of copending Application No. 09/443,863. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims in both applications are drawn to the same method of preparing the microparticles. The method claims in the copending application recite in addition the step of adding the bulking/releasing agents in order to prepare rapidly disintegrating solid dosage forms and the independent claims in addition recite 'water insoluble or poorly water soluble drug'. However, the dependent claims (129-131 for example) specify that the drug is fenofibrate. It would have been obvious to one of ordinary skill in

the art to utilize additional steps in instant process to prepare appropriate dosage forms of fenofibrate such as rapidly disintegrating forms claimed in the copending application. Instant species of the drug, 'fenofibrate' is anticipated by the generic 'water insoluble drug' in the claims of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 34-36, 38-48, 50, 52 and 55-67 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-37 of copending Application No. 09/443,862. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims in both applications are drawn to the same method of preparing the microparticles. The method claims in the copending application recite in addition 'water insoluble or poorly water soluble drug' and a formula to achieve an overall HLB value for the system. Instant claims are generic with respect to the system HLB values. It would have been obvious to one of ordinary skill in the art to prepare the drug particles with a desired HLB values with a reasonable expectation of success since this depends upon the intended use of the particles. Instant species of the drug, 'fenofibrate' is anticipated by the generic 'water insoluble drug' in the claims of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is

(571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK